

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESAL PRICE LITIGATION	) ) ) )	MDL NO. 1456 Civil Action No. 01-12257-PBS Subcategory Case No. 03-10643-PBS
THIS DOCUMENT RELATES TO:  <i>The City of New York, et al.,</i> v. <i>Abbott Laboratories, et al.</i>	) ) ) ) ) ) )	Judge Patti B. Saris

**PLAINTIFFS' MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' JOINT  
MOTION FOR SUMMARY JUDGMENT ON PLAINTIFFS' "FUL FRAUD" CLAIMS  
AND IN FURTHER SUPPORT OF PLAINTIFFS' MOTION FOR PARTIAL SUMMARY  
JUDGMENT ON THEIR § 145-B CLAIM**

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## INTRODUCTION

### A. Section 145-b

Plaintiffs' opening papers establish that the FUL Thirteen<sup>1</sup> knowingly reported WACs that did not reflect actual prices to customers. *See e.g.*, plaintiffs' memorandum of law in support of their motion for partial summary judgment filed May 15, 2009 [Dkt. No. 6077] ("Pl. FUL Br.") at n.13; Appendix A to Pl. FUL Br.; Plaintiffs' Individual Local Rule 56.1 Statements of Undisputed Material Facts as to each of the FUL Thirteen Defendants. [Dkt. Nos. 6060-6077]; Declaration of Harris L. Devor, dated May 15, 2009, and submitted in support of plaintiffs' motion ("Devor Dec.") [Dkt. No. 6061]. Defendants' motion makes no attempt whatsoever to deny that what they reported were not actual prices to customers; nor do defendants attempt to show the truthfulness of what they did report.<sup>2</sup> Instead, defendants argue that plaintiffs cannot establish causation or liability as to any of their claims. Defendants misapprehend the elements of plaintiffs' claim under New York Social Services Law § 145-b ("Section 145-b").

Neither causation nor deception is an element of a Section 145-b claim. Liability rests upon the "attempt to obtain" payment "by means of a false statement or representation or by deliberate concealment of any material fact or other fraudulent scheme or device on behalf of himself or others." N.Y. Soc. Serv. L. § 145-b (1)(a). It is apparent, therefore, that a Section

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<sup>1</sup> The terms of art employed in Plaintiffs' FUL Brief are incorporated herein.

<sup>2</sup> This Court has held that a "true" WAC is "the price that wholesalers actually paid to acquire the drug." *Commonwealth of Massachusetts v. Mylan Laboratories*, 2008 WL 5650859, at \*15 (D. Mass. Dec. 23, 2008). Defendants present no record evidence whatsoever to establish the truthfulness of their WACs. Plaintiffs' Response to Defendants' Local Rule 56.1 Statement of Undisputed Facts ("Pl. 56.1 Response") at ¶ 67, *e.g.*

145-b claim may be pursued successfully even where the scheme fails to deceive, and this Court has held Section 145-b applicable to the facts at bar:

Though the providers may in fact have pocketed the spread, defendants realized the benefit of their fraud in the form of increased sales and market share, inclusion of their drugs in various formularies, and exclusivity arrangements with wholesalers and other providers. Moreover, under the definition of ‘obtain’, a party receives public funds if it receives payment from any entity that is reimbursed from such funds.

*In re Pharm. Indus. Average Wholesale Price Litig.*, 2007 WL 1051642, at \*11 (“*NY Counties I*”) (citations omitted).

Defendants nevertheless insist that it matters that one or more persons within CMS or New York Medicaid may have known that there were differences between the prices published in the national pricing compendium and actual transaction prices. *See* defendants’ memorandum in support of their joint motion for summary judgment on plaintiffs’ “FUL Fraud” claims (“Def. FUL Br.”) at 20-23. But, apart from the fact that Section 145-b does not require actual deception or causation of out-of-pocket damages (Pl. FUL Br. at 16-17), agency “knowledge” does not come into being unless the agency had “knowledge of the actual true facts of the claim, not simply knowledge that the claim is generally false,” or “the government was defrauded by the very activities its agents ordered,” and knowledge of one agency is not imputed to another. *Mylan*, 2008 WL 5650859, at \*19-20.<sup>3</sup> There is no record evidence whatsoever, and

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<sup>3</sup> *See also E.F.S. Ventures, Corp. v. Foster*, 71 N.Y.2d 359, 370, 520 N.E.2d 1345 (1988):

Generally, governmental agencies are not subject to the defense of estoppel for two reasons. First, the doctrine is not applied against the government, as a matter of policy, because to do so could easily result in large scale public fraud. \* \* \* The second, and

defendants' motion does not suggest otherwise, that CMS or New York Medicaid knew any of the pertinent "actual true facts", viz., (a) that defendants' WACs did not reflect actual prices, or (b) that CMS or New York Medicaid knew the actual true WACS, or (c) that CMS or New York Medicaid knew the actual inflation. *See, e.g.*, Pl. 56.1 Response at ¶¶ 40, 57-62; Declaration of Susan E. Gaston, sworn to June 15, 2009 ("Gaston Dec.") at ¶ 6 (Attached as Exhibit C to the Affidavit of Joanne M. Cicala, submitted in opposition to Defendants' Motion, dated June 15, 2009 ("Cicala Opp. Aff.")). There is no hint that any government agent ordered or wittingly participated in the activities complained of. *Id.* Accordingly, defendants may not deflect the impact of Section 145-b by interposing what amounts to a government knowledge defense.

Nor can defendants persuade that damages are too imprecise or speculative to allow for recovery under Section 145-b. (Def. FUL Br. at n.10.) Section 145-b provides its own damage measurement protocol: plaintiffs "shall have the right to recover civil damages equal to three times the amount by which any figure is falsely overstated ...." N.Y. Soc. Serv. L. § 145-b(2). Under this strict and easily performed formula, a local district or the state may recover damages (trebled) even where defendants' false presentment fails to dupe. It is the "attempt to obtain", not the success of the scheme, that imposes liability. *See* N.Y. Soc. Serv. L. § 145-b(1)(a); Pl. FUL Br. at 16. False reporting acts aim to prevent false reports, not provide false reporters with free passes whenever their schemes fail. In the event, defendants' arguments addressed to the inability to calculate damages with adequate precision bear no weight insofar as Section 145-b is concerned. Defendants' attacks on other claims also lack force.

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more fundamental, reason why estoppel is not generally permitted against the government is that to do so may violate the doctrine of separation of powers.



## B. Section 349/Common Law Fraud

Defendants claim that causation is a necessary element for each cause, and plaintiffs cannot satisfy causation because of “the undisputed record evidence demonstrating that CMS routinely disregarded lower published prices in order to achieve important (and competing) policy objectives.” Def. FUL Br. at 15-18.

The undisputed record evidence is that (a) the “starting point” for the determination of every FUL was a WAC (*see* Def. FUL Br. at 5; Gaston Dec. at ¶ 3), and (b) every defendant-provided, reported, or published WAC was false. *See* Indiv. 56.1 Statements as referenced at Pl. FUL Br. at n.13. Undisputable too is that defendants’ expert presents no record evidence whatsoever to support that the generic manufacturers’ WACs were true, and they were not. Pl. 56.1 Response at ¶¶ 67, *e.g.* Defendants’ failure to supply any data showing the truth of their reports cannot be mere dereliction. They provided precisely this information in defending brand WACs. *See* Schering’s motion for a protective order, filed May 13, 2008 [Dkt. No. 5296] and affidavit of Sumanth Addanki, dated February 21, 2008, in support [Dkt. No. 5299]; declaration of Sumanth Addanki from MDL Track One Trial, filed December 1, 2006 [Dkt. No. 3430]; *In re Pharm. Indus. Average Wholesale Price Litig.*, 491 F. Supp. 2d 20 (D. Mass. 2007) (“*Track One Trial*”)<sup>4</sup>.

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<sup>4</sup> In each of these submissions, defendants’ expert performed a WAC List Price Test analysis or AWP/AMP spread test to demonstrate either (a) that more than 50% of defendants’ sales were within 5% of WAC and/or (b) that the spreads between AMP and reported AWP were less than the 30% speed limit utilized by this Court in the MDL Track One Trial (*see* n.6, *infra*). Defendants’ expert conducts neither test in connection with the instant motion because defendants are entirely aware that the results would demonstrate – for every single NDC in every single quarter the rampant falsity of every single WAC and AWP they reported. *See* Indiv. 56.1 Statements as referenced at Pl. FUL Br. at n.13.

Undisputed as well is that this litigation concerns itself with only materially false reports, a necessary by-product of the Court's ruling that inflations over 30% were beyond payor expectations.<sup>5</sup> To put a sharper point on record evidence – defendants offer none of any kind that, during the relevant time period, (a) defendants ever provided, reported, or published true WACs, or (b) CMS or New York Medicaid knew that defendants always were reporting inflated WACs, or (c) that CMS or New York Medicaid knew the actual true WACs, or (d) that CMS or New York Medicaid knew the degree of inflation or the true WACs. And, again, defendants never could provide that record evidence because it would contradict established reality. *See* n.5, *supra*.

Defendants helpfully point out that, “In practice, CMS had a computer program - the ‘FULs system’ - that gathered the published prices from (AWPs, WACs, and DPs) from the national pricing compendia,” which represented the “*starting point*” for a review involving some discretionary selections (Def. FUL Br. at 5, emphasis in original.) Defendants gloss over the critical point. Because defendants’ actions had led to unremittingly false published prices in the national pricing compendia, defendants assured that the government’s “*starting point*” *always* rested on false premises.

Properly framed, therefore, defendants’ proposition is this: “We cannot be held accountable for fraud or deceit where, notwithstanding a regulated duty, we systematically

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<sup>5</sup> The 30% speed limit was established in the context of the MDL Track One Trial which involved private Third Party Payors. *See Track One Trial*, 491 F. Supp. 2d at 92. It is unresolved if this limit applies in the Medicaid context, and this Court has repeatedly acknowledged plaintiffs’ right to file an expert affidavit on the point. Plaintiffs expressly reserve that right but emphasize that the issue is largely irrelevant in the context of this FUL briefing, given the pervasive mega-spreads. *See* Individ. 56.1 Statements as referenced at Pl. FUL Br. at n.13.

submitted materially false data to persons who may have known that some data was inaccurate but who (a) did not know that we invariably supplied false data; (b) did not know the true data; and (c) did not know the extent of the deviation from the true.” Put otherwise, defendants’ ludicrous proposition is that people who may occasionally leave a penny change on the counter are equally indifferent to a \$20 overcharge.

This line of attack also collides with the law in this case – and law generally – that concerns government knowledge. Defendants insist that they could not have deceived plaintiffs and consequently could not have caused compensable harm because governmental agencies had knowledge that reported and transactional prices did not always keep company, or because CMS did not always select the lesser FUL. Def. FUL Br. at 4-6, 21. But we have just rehearsed the Court’s statement of the elements required to mount a defense based upon government knowledge (*see* pp. 2-3, *supra*), and defendants satisfy none of them. There is no record evidence, and we assure that there can never be, that plaintiffs or CMS or New York Medicaid knew that defendants had been supplying an entirely corrupt data base, or that plaintiffs or CMS or New York Medicaid knew the actual true data, or even the degree of inflation. *See* Gaston Dec. at ¶¶6; Pl. 56.1 Response at ¶¶ 40, 57-62<sup>6</sup> This Court has repeatedly rejected the “absurd” proposition that defendants’ reported prices need not be tethered to actual transaction prices or that defendants were free to report any price they wished. *See Track One Trial*, 491 F. Supp. 2d at 97 n.72 (“defendants’ proposed statutory interpretation that Congress intended AWP to be a blank check to the industry to impose whatever markup it wanted is supported nowhere in the

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<sup>6</sup> Defendants’ arguments regarding recent events as to whether a FUL should be set at 250% of AMP are entirely irrelevant to defendants’ obligations to report accurate prices to the

legislative or trial record”); *Mylan*, 2007 WL 5650859, at \*15 (if WAC not tied to the “real price charged to most wholesalers” leads to an “absurd result”).<sup>7</sup> And, in 1987, when the FUL regulations were initially passed, the record evidence is that HCFA expected the spread between the published prices for generic drugs and acquisition costs for generic drugs to be in the same range as brands (20-25%). *See* Medicare and Medicaid Programs: Limits on Payment for Drugs 51 Fed. Reg. 29,560 (Aug. 19, 1986); *see also* plaintiffs’ memorandum of law in opposition to defendants’ joint motion to dismiss (Dkt. No. 4452) at 16-18. There is no record evidence that when HCFA elected to set the FUL at 150% of published prices, HCFA accepted or endorsed the complete disconnect between published and actual prices or the mega-spreads that are now well documented. In all, the most that defendants muster is the naked claim that CMS’s possible access to sources of information other than defendants’ false reports “must have informed CMS” that defendants were routinely reported completely false, untethered and wildly inflated numbers. Def. FUL Br. at 20-21.

What are the “other sources” to which defendants refer? AMPs and AWP. Def. FUL Br. at 8-9. But AMPs are statutorily prohibited from being used for reimbursement. *See* Gaston Dec. at n.1. CMS could not have started to use AMPs as a basis for reimbursement without changing the law, which was not in its power to do. *See* n.16, *infra*. Moreover, AMPs

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government and the question of whether defendants’ abided such obligations. *See* Pl. R. 56 response at ¶¶ 44-56

<sup>7</sup> Furthermore, this is contrary to the Court’s ruling that WAC mean “the price that wholesalers actually paid to acquire the drug”. *Id.*

are not published, confidential and not WACs.<sup>8</sup> And defendants' reported AWP's were even more grotesquely inflated than their WACs. *See* Exhibit C to Devor Dec. [Dkt. No 6061]. This at once leads to and destroys defendants' alternate ground that CMS should have been unstintingly *en garde* against fraud. Def. FUL Br. at 8-9, 20. Apart from the inutility or unavailability of AMP data, defendants offer up this proposition without authority<sup>9</sup> against the various laws and regulations that oblige defendants to report truthful data<sup>10</sup>, and that punish for even failed attempts to misrepresent.<sup>11</sup> In short, neither law nor regulation places the burden of gathering or verifying on the government.

Defendants' remaining claim is that, assuming liability, there can be no damages because "plaintiffs cannot possibly prove what CMS would have done had defendants submitted lower prices to the compendia." Def. FUL Br. at 17, and n.10. First, the argument misapprehends the law of remedies. "[U]nder the long-standing New York rule, when the

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<sup>8</sup> AMPs are defined by statute: "the term 'average manufacturer price' means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs *distributed to the retail pharmacy class of trade*." 42 U.S.C. 1396r-8(k)(1)(A) (emphasis added). WACs, however, are the wholesaler's acquisition cost for *all drugs purchased, regardless of the end customer*. *See Mylan*, 2008 WL 5650859, at \*12-13 (citing an August 2004 report done by Abt Associates for CMS).

<sup>9</sup> *See U.S. ex rel. Cantekin v. University of Pittsburgh*, 192 F.3d 402, 408 (3d Cir. 1999). Congress, by adding the 1986 False Claims Act amendments making it easier to bring a *qui tam* action, recognized "(1) the government lacks the resources to investigate and prosecute all false claims even when the government has information revealing fraud; (2) a government official who is deemed to "have" the information may not recognize the connection between the information and a particular false claim; (3) the official may have an interest in not bringing the fraud to light for a number of reasons, such as an interest in protecting the official's or the agency's reputation . . . ." Defendants offer no support whatsoever for the proposition that New York's legislature intended to hold its agencies to a higher standard under Section 145-b.

<sup>10</sup> *Heckler v. Community Health Servs.*, 467 U.S. 51, 63-65 (1984); 68 Fed. Reg. 23731-01, at 23732-4 (May 5, 2003).

existence of damage is certain, and the only uncertainty is as to its amount, the plaintiff will not be denied a recovery of substantial damages.” *Contemporary Mission, Inc. v. Famous Music Corp.*, 557 F.2d 918, 926 (2d Cir. 1977). *See also* Point II, *infra*. Second, the CMS deposition testimony and Gaston Declaration make clear that, had CMS been presented with accurate lower WACs, CMS would have considered those and, in all likelihood, would have issued a lower FUL because, among other things, low prices that appeared to be outliers would no longer have appeared or been outliers. *See* Gaston Dec. at ¶¶ 7-17; Pl. 56.1 Response at ¶¶ 7-31.

## ARGUMENT

### **I. DEFENDANTS OFFER NO MEANINGFUL DEFENSE TO LIABILITY UNDER § 145-b. ACCORDINGLY PARTIAL SUMMARY JUDGMENT IS APPROPRIATE**

There is little to add to our introductory remarks, which we now highlight only. Defendants do not deny that their reports were false, saying only that plaintiffs should have been constantly vigilant of fraud, and had they dutifully mistrusted what defendants were duty bound to report honestly, the truth might have been discovered from other sources. Def. FUL Br. at 20-21.

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<sup>11</sup> N. Y. Soc. Serv. L. § 145-b.

Defendants’ only claim is that plaintiffs cannot demonstrate deception or causation. Def. FUL Br. at 15, 19. Plaintiffs contest this assertion, but nevertheless, it is unavailing, as neither causation nor deception, *per se*, is an element of a Section 145-b claim.<sup>12</sup> As stated in plaintiffs’ moving brief, false claims acts focus on preventing defendants’ bad behavior, sharing with all false reporting law the desire to discourage false reports. Thus, Section 145-b attaches liability upon the “attempt to obtain” improper payments and imposes damages by a trebling of the spread between true and false overstatement. Pl. FUL Br. at 16-17. By the explicit terms of Section 145-b, liability and damages require neither an actual deception nor out of pocket losses – although both have merit here. Defendants make no showing that they satisfy the tests for governmental knowledge. *See* pp. 2-3, *supra*. A discussion of authorities concerning the False Claims Act and certainty of measurement of damages appears at Point II.B, *infra*.

## **II. DEFENDANTS HAVE NOT SUSTAINED THEIR RULE 56 BURDENS WITH RESPECT TO N.Y. GBL § 349 OR COMMON LAW FRAUD. ACCORDINGLY, DEFENDANTS’ MOTION SHOULD BE DENIED**

### **A. Causation and Deception**

“The government is indifferent to fraud and indifferent to its costs.” That is defendants’ underlying thesis. Unsurprisingly, there is no record evidence of that. There is simply nothing in the record that establishes government knowledge of true WACs, or knowledge that

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<sup>12</sup> As defendants note, there is a paucity of caselaw interpreting Section 145-b. However, neither the language of the statute nor the cases that do interpret it include an element of causation. Nor, contrary to defendants’ assertion at page 20 of their brief, does this Court state that a party must prove that it was deceived. Nowhere in *NY Counties I* did this Court rule that plaintiffs must show that they were deceived by defendants’ false statements or deliberate concealments. Rather, this Court merely stated that “Because Section 145-b applies to false

defendants always submitted false WACs, or that inflation exceeded 30%. *See* Pl. 56.1 Response at ¶¶ 57-62; Gaston Aff. at ¶ 6. Defendants concede that the “*starting point*” for each CMS review of FULs was based upon a national pricing compendia that the record shows always was false and always because of defendants’ false reports. Def. FUL Br. at 5; Indiv. 56.1 Statements as referenced at Pl. FUL Br. n.13. Defendants do not and cannot show that, as matter of law, had the federal government or New York Medicaid known any of this information, much less all of it, it would not have considered that information, but would have continued to select systematically and grossly inflated WACs. The Gaston Declaration is to the contrary. Gaston Dec. at ¶ 7.

Two prior decisions of this Court provide the legal bases for rejection of this part of defendants’ argument. The first, of course, is that the Court has laid down the law on governmental knowledge. *See Mylan*, 2008 WL 5650859, at \*19-20. As applied, defendants need to show that the government knew the actual true WACs, knew that defendants always were exaggerating them, and knew the extent of their inflation. *See id.* There is no record evidence of any of this knowledge. Pl. 56.1 Response at ¶¶ 57-63. Gaston Dec. at ¶ 6.

The other ruling is equally uncontroversial: A may deceive C by delivering deceptive information to B who passes it along to C. Addressing this very point in *New York Counties I*, this court wrote:

In *Eaton*, 83 N.Y. at 34-35, New York’s highest court held that a misrepresentation made to one party, which the maker intends to be communicated to and influence a third party, is actionable in fraud by the third party if he relies on the misrepresentation to his detriment. The court explained:

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statements, deliberate concealments, or other fraudulent schemes or devices Rule 9(b) applies to this claim.” *NY Counties I*, 2007 WL 1051642, at \*14 (internal citations omitted).



“If A. casually or from vanity makes a false or exaggerated statement of his pecuniary means to B or even if he does so with the intent to deceive and defraud B and B communicates the statement to C. who acts upon it, A cannot be held as for a false presentation to C. But if A makes the statement to B. for the purpose of being communicated to C or intending that it shall reach and influence him, he can so be held.”

*New York Counties I*, 2007 WL 1051642, at \*13, with continuing discussion *et seq.*

None of the exceptions to this basic principle applies. The injuries were neither “inchoate or unintended” nor “remote” (*see id.* at \*14); defendants provided knowingly false and purposeful data, which, when relied upon by predictable third-parties, caused injuries.

Nor is there anything for defendants to make of the fact that New York law obliges New York Medicaid to reimburse all drugs “for which CMS had established a FUL at the upper limit set by CMS.” Def. FUL Br. at 13, 18. Mr. Perales’ 1986 letter surmises that setting FULs on “advertised” or “quoted” prices for 100 mg capsules will not lead to cost savings given that most pharmacies buy in larger cheaper quantities. Pl. 56.1 Response at ¶ 59. His letter says nothing about inflation or falsity of WAC and nothing about the extent of any WAC inflation. Pl. 56.1 Response at ¶¶ 57-63. In short, the Perales letter does not governmental knowledge make. In addition to its failure to satisfy the required elements of governmental knowledge, there is no evidence that Mr. Perales conveyed his views to the legislature, which – eight years later – enabled the law.<sup>13</sup> So, even had Mr. Perales all the information about false reports (and there is no record evidence that he did), and had provided New York Medicaid with all the information about false reports (again, there is no record evidence that he did), the knowledge of

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<sup>13</sup> N.Y. Soc. Serv. Law §367-a(9)(b)(i) (McKinney 1994).

the one government agency would not be imputed to another – the more so if the other were an entirely different branch.<sup>14</sup> *See Mylan*, 2008 WL 5650859, at \*20.

Moreover, that CMS did not use the lowest false price does not mean that defendants' false prices were not the cause of an inflated FUL. Had CMS been presented with an array of *accurate* (and therefore lower) prices and behaved the same way, the FUL would have been lower regardless of which *true* price would have been selected.<sup>15</sup> *See Gaston Dec.* at

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<sup>14</sup> If what defendants mean to say is that a member of the executive branch had or could have taken it upon himself to re-write the law, that argument would be brought to a sharp halt by separation of powers and related doctrine. It is black-letter law that the legislature has the sole authority to make law. *See Kilbourn v. Thompson*, 103 U.S. 168, 190-191 (1880). The executive branch does not have the power to alter or amend the law:

“Legislative power” is the power to make, alter, and repeal laws and to formulate legislative policy; and “executive power” is the power to put laws enacted by the legislature into effect. It is clear that the executive can neither encroach upon the functions of the legislature nor interfere in its duties; neither can the executive discharge the functions of the legislature in any manner by so acting in his or her official capacity that his or her conduct is tantamount to a repeal, enactment, variance, or enlargement of legislation.

16A Am. Jur. 2d Constitutional Law § 258 (2009). *See also In Interest of C.S.*, 516 N.W.2d 851, 859 (Iowa 1994) (in considering whether the legislature's delegation of authority to determine whether out-of-state placement of a mentally ill child violated separation of powers clause, the court articulated that basic principle that “Legislative power is the power to make, alter, and repeal laws and to formulate legislative policy. Executive power is the power to put the laws enacted by the legislature into effect.”) (internal citations omitted).

One branch of government cannot dictate to another. *See Washington v. Washington State Commercial Passenger Fishing Vessel Ass'n.*, 443 U.S. 658, 694 (1979) (attorney general's representations that resolution of basic federal question of construction of Indian treaty fishing rights would remove any state law impediment to enforcement of the State's obligations under the treaties were not binding on the judicial or legislative branches, although authoritative within the executive branch).

<sup>15</sup> Defendants' attempt to paint this as an “alternative theory of causation” (Def. FUL Br. at 18) is unavailing, and, in fact, inexplicable, as this is the very heart of plaintiffs'

¶¶ 10, 12, 15, 17. It simply does not follow that a loser in a rigged game would be happy to suffer the same losses in an honest one.

In all, a reasonable fact-finder could find that defendants' false and inflated published prices caused CMS to set an inflated FUL and therefore caused FUL-based reimbursements to have been higher than they should have been. Genuine controversies exist concerning these matters. In the event, defendants' motion for summary judgment must fail.

A reasonable fact finder likewise could find that CMS's reliance on WACs was reasonable. As in the *Mylan* case, there is simply no record evidence that CMS's knowledge as to the falsity of defendants' WACs was as defendants suggest.

[a]lmost all publicly available information appearing through the end of the Damage Period suggested that participants and informed analysts of these markets believed that  $WAC + x\%$ , where  $x\%$  was reasonably small, provided a good approximation of the actual drug acquisition cost for retail pharmacies. The only information that I have seen to the contrary is that found in the March 2002 OIG Report discussed ... above. That information was certainly insufficient to have altered the Commonwealth's reimbursement practices through 2003:Q1.

*Mylan*, 2008 WL 5650859, at \*28.

That CMS had access to defendants' AMPs does not establish, much less as a matter of law, that CMS could not have reasonably relied on the reported WACs. AMP is not the same as WAC. As discussed in n.9, *supra*, AMP is statutorily defined as the average manufacturers' price to wholesalers but only for drugs resold to the retail class of trade, while WAC is the wholesaler's acquisition cost for all drugs purchased, regardless

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claim. Plaintiffs contend that "had defendants submitted accurate prices to the pricing compendia, the FULs set by CMS would have been lower and the New York State Medicaid Program would have paid less." Revised First Amended Consolidated Complaint at ¶ 14.

of the end customer. *See Mylan*, 2008 WL 5650859, at \*12-13 (citing an August 2004 report done by Abt Associates for CMS). Moreover, federal statutes prohibit the use of AMPs for reimbursement purposes (*see* Medicare Improvements for Patients and Providers Act of 2008, Pub. L. No. 110-275, 122 Stat. 2494 (2008) (MIPPA)) and require that AMPs be held confidentially (*see* 42 U.S.C. 1396r-8(b)(3)(D)). *See also* Gaston Dec. at ¶ 6. Given that AMP is not WAC and that AMP is confidential and cannot be used for reimbursement, a reasonable fact finder could find that even a CMS possession of AMPs would not render unreasonable CMS's use of WACs for FUL purposes.

#### **B. Measurement of Damages**

“Plaintiffs also could not prove damages even if they overcame all of these hurdles because damages would be too speculative with the discretion exercised by CMS in setting FULs,” write defendants at page 23, n.10 of their brief. No authority is supplied. The actual rule of law is *contra* defendants’ *ipse dixit*.

“[U]nder the long-standing New York rule, when the existence of damage is certain, and the only uncertainty is as to its amount, the plaintiff will not be denied a recovery of substantial damages.” *Contemporary Mission, Inc. v. Famous Music Corp.*, 557 F.2d 918, 926 (2d Cir. 1977).

However, it is defendants – not plaintiff – who must bear the risk of any uncertainty which their wrong has created. Where the complained of injury “is of such a nature as to preclude the ascertainment of the amount of damages with certainty, it would be a perversion of fundamental principles of justice to deny all relief to the injured person, and thereby relieve the wrongdoer from making any amend for his acts.”

*Schoenholtz v. Doniger*, 657 F. Supp. 899, 908 (S.D.N.Y. 1987) (quoting *Story Parchment Co. v. Patterson Co.*, 282 U.S. 555, 563 (1931)).<sup>16</sup> See also 16 N.Y. Prac., New York Law of Torts § 21:10 (2008):

The general rule in tort law is that there must be certainty in proof as to the existence of plaintiff's injury, harm or loss. This rule, however, does not bar the recovery of damages when the extent of the harm is uncertain and not capable of precise determination or measurement. ... Stated otherwise, a wrongdoer will not be shielded from liability because damages are incapable of precise measurement.

“[T]he jury could have rationally awarded damages in an amount representing the ‘best approximation possible through the exercise of good judgment and common sense’. Recovery will not be denied merely because the quantum of damages is uncertain or difficult to ascertain.” *Shoecraft v. BBS Automotive Group, Inc.*, 853 N.Y.S.2d 125, 126 (2nd Dep’t. 2008) (quoting *Matter of Rothko*, 43 N.Y.2d 305, 323 (1977)).

*Curiale v. Peat, Marwick, Mitchell & Co.*, 630 N.Y.S.2d 996 (1<sup>st</sup> Dep’t 1995), has special bearing. Defendant accounting firm was found liable for malpractice errors that had caused a damaging delay in a court administered rehabilitation of several insolvent insurance companies. The defendant firm had argued that:

there is no evidence as to how quickly the rehabilitation proceeding could have gone to trial or what the justice presiding in

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<sup>16</sup> See also *Berley Industries, Inc. v. City of New York*, 45 N.Y.2d 683, 687, 385 N.E.2d 281 (1978) (plaintiff who proves injury is not denied recovery because “the quantum of damage is unavoidably uncertain, beset by complexity or difficult to ascertain”); *Steitz v. Gifford*, 280 N.Y. 15, 19 N.E.2d 661 (1939); *Borne Chemical Co., Inc. v. Dictrow*, 445 N.Y.S.2d 406 (App. Div. 1981) (fact that plaintiff sustained damage must be proved with certainty, but nothing like precise mathematical accuracy can be obtained); *Tobin v. Union News Co.*, 239 N.Y.S.2d 22 (4th Dep’t 1963), *aff’d*, 13 N.Y.2d 1155, 196 N.E.2d 735 (1964) (difficulty of assessing damages does not excuse their determination and uncertainty in amount does not bar recovery).

that proceeding *would have* done if the case had gone to trial, or how quickly the justice *would have* acted. Indeed, the defendant notes that when the Insurance Department urged the court to take immediate action to enter an order of rehabilitation, the judge continued to put off hearing dates and substitute conference calls in the hope that the parent or subsidiaries would do better . . .

*Id.* at 1001 (emphasis added.) The argument there is essentially defendants’ argument here: because damages may have been influenced by the discretionary action of a third party – there a judge, here CMS – and because there may be a degree of speculation about what would have been done, damages are too speculative to award. The court in *Curiale* rejected this defense, ruling that a jury could effectively consider defendants’ “imponderables” and appropriately determine a measure of damages. *See id.* at 1002. The fact finder “had the right to resort to reasonable conjectures and probable estimates and to make the best approximation possible through the exercise of good judgment and common sense in arriving at that amount [citations omitted]. This is particularly so where the conduct of wrongdoers has rendered it difficult to ascertain the damages suffered with the precision otherwise possible.” *Id.* at 1001 (citing *Rothko, supra*).

Several cases decided under the Federal False Claims Act have held that the uncertainty involved in the calculation of damages is no bar to their award. In *Miller v. Holzmann*, 563 F. Supp. 2d 54 (D.D.C. 2008), a defendant challenged the method purportedly adopted by the jury in apportioning damages amongst various defendants in a bid rigging conspiracy under the FCA. The court rejected the argument out of hand, quoting *Bigelow v. RKO Radio Pictures, Inc.*, 327 U.S. 251, 264 (1946): “where the defendant by his own wrong has prevented a[ ] precise computation” of damages, the jury “may make a just and reasonable estimate of the damage based on relevant data.” *Id.* at 108. The *Holzmann* court went on:

In reviewing the amount of the jury's award, [the court] need not—and indeed cannot—reconstruct the precise mathematical formula that the jury adopted. Nor need [it] explore every possible quantitative analysis or compute the basis of every penny and dollar in the award. [Its] inquiry ends once [it is] satisfied that the award is within a reasonable range and that the jury did not engage in speculation or improper activity.

*Id.* at 143 n.141 (citing *Carter v. Duncan-Huggins, Ltd.*, 727 F.2d 1225, 1239 (D.C. Cir. 1984)). See also *Faulk v. U.S.*, 198 F.2d 169 (5<sup>th</sup> Cir. 1952), a false claims act case. There, a purveyor to the army falsely claimed reconstituted milk to be Grade A fresh. Damages were calculated by roughly estimating how much each bottle of the reconstituted milk was left undrunk by a soldier because of poor taste relative to fresh milk. “Under such circumstances there is no merit whatever in appellant's contention that merely because the Government was unable to prove with absolute mathematical accuracy the amount of milk unconsumed by the troops it was not entitled to recover double damages under the statute.” *Id.* at 173. The court quoted *Bigelow* at length.

Two other FCA decisions are notable for holdings establishing damages, particularly because they suggest that hypothetical considerations of what may have happened had the false claim not been submitted need not limit damages. In *U.S. v. Hawley*, 544 F. Supp. 2d 787, 810 (N.D. Iowa 2008), defendant argued that the government would have have been required to pay insurance on a failed crop to the true owner of the crop, even if he had not falsely claimed the crop as his own.

The question is not whether the government would have paid or approved the same claim submitted *by somebody else* on the basis of the same documents submitted *by somebody else*, but whether the government actually paid the claim actually submitted on the basis of the false documents submitted by the persons who actually submitted them.

*Id.* at 810 (emphasis in original).

In *U.S. v. Rogan*, 517 F.3d 449 (7<sup>th</sup> Cir. 2008), a medical center submitted reimbursement claims to Medicare for services it claimed to have provided to patients obtained through illegal referrals and kickbacks. The Stark Amendment to the Medicare Act, 42 U.S.C. § 1395nn, forbids federal reimbursement for services that stem from compensated referrals, and the United States brought suit under the FCA. Dismissing the fact that many of the patients for whom claims were submitted received some medical care, the court rejected the argument that the government might have had to pay for the care elsewhere:

Now it may be that, if the patients had gone elsewhere, the United States would have paid for their care. Or perhaps the patients, or a private insurer, would have paid for care at [the medical center] had it refrained from billing the United States. But neither possibility allows [the defendant] to keep money obtained from the Treasury by false pretenses, or avoid the penalty for deceit.

*Id.* at 453.

Accordingly, causation, deception, and ascertainability of damages do not bar prosecution of claims either under Section 349 or common law fraud.



## CONCLUSION

For all the foregoing reasons, plaintiffs respectfully request that defendants' joint motion for summary judgment be denied, and that plaintiffs' motion for partial summary judgment be granted.

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Respectfully submitted,

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